Patent Submission Sample Format

This is a format suggestion for submission of patent information for NDAs submitted under section 505 of the Federal Food Drug and Cosmetic Act. For more detailed information please refer to 21 C.F.R. 314.53.

Time Sensitive Patent Information pursuant to 21 C.F.R. 314.53 for NDA #_____

The following is provided in accordance with the Drug Price Competition and Patent Term Restoration Act of 1984:

Trade Name:
Active Ingredient(s):
Strength(s):
Dosage Form:
Approval Date:

A. This information should be provided for each individual patent submitted.

U.S. Patent Number:

Expiration Date:

Type of Patent--Indicate all that apply:

Drug Substance(Active Ingredient) ___Y ___N
Drug Product(Composition/Formulation) ___Y ___N
Method of Use ___Y ___N

a. If patent claims method(s) of use, please specify approved method(s)of use or method(s) of use for which approval is being sought that are covered by patent:_____

Name of Patent Owner:

U.S. Agent (if patent owner or applicant does not reside or have place of business in the US):

B. The following declaration statement is required by 21CFR 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Patent Number _____ covers the composition, formulation and/or method of use of _____(name of drug product). This product is:

___currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act)

OR

___the subject of this application for which approval is being sought.)

Signed:

Date:

Title (optional):

Telephone Number (optional):

The above information should be submitted to the NDA with the original application or as correspondence to an existing NDA. For patents issued after the NDA is filed or approved, the applicant is required to submit the information within 30 days of the date of issuance of the patent.

To expedite publication in the The Orange Book,* the above information may be provided to the Division of Data Management and Services at the address below. You may also contact the Division of Data Management and Services directly at (301)827-5467 regarding listing of patent information.

Mailing address: (US Mail)
U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services
Information Services Team
HFD-93
5600 Fishers Lane
Rockville, MD 20857

OR

Location address: (for FedEx deliveries)
U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services
Information Services Team
HFD-93 Room #3012
12420 Parklawn Drive
Rockville, Maryland 20857-0001

OR faxed to: (301)-594-6463

* - Please note that patents for unapproved compositions, formulations, or uses will NOT be published in the The Orange Book.